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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,865	03/16/2004	Jane Ye	CL001143DIV	2172

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CELERA GENOMICS
ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY
45 WEST GUDE DRIVE
C2-4#20
ROCKVILLE, MD 20850

EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	PAPER NUMBER
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,865	YE ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 24-38* is/are pending in the application.

4a) Of the above claim(s) *1,2,37 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 24-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The election with traverse filed October 26, 2006, is acknowledged and has been entered.

Applicant has elected the invention of Group II, claim 3, drawn to an antibody.

2. The amendment filed October 26, 2006, is acknowledged and has been entered. Claims 4-23 have been canceled. Claims 1-3 have been amended. Claims 24-38 have been added.

3. Claims 1-3 and 24-38 are pending in the application. Claims 1, 2, 37, and 38 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

4. Claims 3 and 24-36 are currently under prosecution.

Election/Restriction

5. Applicant's arguments traversing the restriction and election requirement set forth in the Office action mailed September 27, 2006, have been carefully considered but not found persuasive for the following reasons:

Applicant has argued the search necessary to examine the claims drawn to the elected invention necessarily include a search of the subject matter encompassed by pending claims directed to non-elected inventions.

In response, M.P.E.P. § 803 states that it is proper to restrict inventions that patentably distinct, each from the others, provided that searching the different inventions would constitute a serious burden.

As explained in the preceding Office action mailed September 27, 2006, antibodies and the antigens (e.g., proteins) to which the antibodies bind are patentably distinct products.

Furthermore, as also noted in the preceding Office action, searching both the invention of Group I (i.e., the polypeptide or fragment thereof) and the invention of Group II (i.e., the antibody that binds the polypeptide) would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, as well as other art-recognized divergences. Additionally, the necessary searches are not the same, nor are they coextensive in nature and scope with one another, since, for example, it is appreciated that an antibody capable of binding the polypeptide need not be an antibody produced using the polypeptide as an immunogen. Commerically available anti-phosphotyrosine antibodies, for example, bind promiscuously to tyrosine-phosphorylated proteins, yet these antibodies were not produced using the tyrosine-phosphorylated proteins as an immunogens. By way of further explanation, antibodies bind epitopes, which are generally only very small portions of much larger antigens; an antibody that binds an epitope shared by more than one antigen could not distinguish one of the antigens from the others. Accordingly, while a search of relevant sequence databases using the entire amino acid sequence of the polypeptide as query is necessary for the determination of the novelty and unobviousness of the polypeptide, such a search is not necessary, or sufficient to identify antibodies that bind the polypeptide. Rather, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search necessary for examination of claims directed to the different inventions would be performed using a different set or series of key words. For these reasons, contrary to Applicant's assertions, having to search both inventions of Groups I and II would constitute a serious burden.

Since the inventions of Groups I and II are patentably distinct and because the examination of both could not be made without serious burden, in accordance with M.P.E.P. § 803, it is proper to restrict one from the other.

Accordingly, restriction and election requirement set forth in the Office action mailed September 27, 2006, is deemed proper and therefore made FINAL.

Drawings

6. The drawings set forth as Figures 2B, 3E, 3F, and 3G are objected to because the figures depict nucleotide and/or amino acid sequences, which are not identified by sequence identification numbers, either in the figure or in the brief description of figure at page 6 of the specification. Sequences appearing in the specification and/or drawings must be identified by a sequence identifier in accordance with 37 C.F.R. 1.821(d); sequence identifiers for sequences appearing in the drawings may appear in the drawings or in the brief description of the drawings.

A replacement drawing sheet, including the correction, is required, if the drawings are objected to. See 37 CFR 1.121(d). However, this ground of objection would be withdrawn, so that a replacement drawing would be not be required, if Applicant were to amend the brief description of the figure at page 5 of the specification to include sequence identification numbers.

Specification

7. The disclosure is objected to for the following reason: The specification contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). Sequences appearing in the specification and/or drawings must be identified by sequence identifier in accordance with 37 C.F.R. 1.821(d). According to 37 CFR § 1.821(a), an unbranched sequence of four or more specifically identified amino acids or an unbranched sequence of ten or more nucleotides must be identified by sequence identification numbers. See MPEP § 2422.01.

In this instance, the nucleotide and/or amino acid sequences depicted in Figures 2B, 3E, 3F, and 3G are not identified by sequence identification numbers, either in the figure or in the brief description of figure at page 6 of the specification.

Applicant must provide appropriate amendments to the specification or drawings inserting the required sequence identifiers. Sequence identifiers for sequences appearing in the drawings may appear in the drawings or in the brief description of the drawings.

As noted in the attached Notice to Comply, appropriate action correcting this deficiency is required. If necessary to correct the deficiency, Applicant must submit paper and computer-readable copies of a substitute sequence listing, together with an amendment directing its entry into the specification and a statement that the content of both copies are the same and, where applicable, include no new matter.

8. The disclosure is objected to because the disclosure refers to embedded hyperlinks and/or other forms of browser-executable code and to the Internet contents so identified. Reference to hyperlinks and/or other forms of browser-executable code and to the Internet contents so identified is impermissible and therefore requires deletion.

Example of such an impermissible disclosures appearing in the specification are found at page 12, lines 5, 10, and 28.

The attempt to incorporate essential or non-essential subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP § 608.01(p), paragraph I regarding acceptable incorporation by reference. See 37 CFR § 1.57.

9. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claims 31-34 are drawn to composition comprising "a pharmaceutically acceptable carrier". While the limitation finds support in original claims (e.g., claim 17), the specification fails to provide proper antecedent basis for the claimed subject matter.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 3 and 24-36 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. 2002/0150916 A1.

U.S. Patent Application Publication No. 2002/0150916 A1 (Meyers) teaches an antibody that binds to a polypeptide comprising an amino acid sequence that is 100% identical to the amino acid sequence set forth in the instant application as SEQ ID NO: 2; see entire document (e.g., SEQ ID NO: 2; paragraphs [0152]-[0171]). Meyer et al. teaches the antibody is a monoclonal antibody; see, e.g., paragraph [0154]. Meyer et al. teaches the antibody is coupled to a detectable substance; see, e.g., paragraph [0169]. Meyer et al. teaches the antibody is formulated as a component of a composition further comprising a pharmaceutically acceptable carrier; see, e.g., paragraph [0304]. Meyer et al. teaches fragments of the antibody, including, for example, a Fab; see, e.g., paragraph [0277].

Conclusion

12. No claim is allowed.

13. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. U.S. Patent Application Publication No. 2004/0048249 A1 teaches an antibody that binds to a polypeptide comprising an amino acid sequence that is 100% identical to the amino acid sequence set forth in the instant application as SEQ ID NO: 2; see entire document (e.g., SEQ ID NO: 278).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is

(571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Primary Examiner
Art Unit 1643

slr
January 8 2007